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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/776,309 | 02/11/2004 | Dilip Tapadiya | TAPADI.003C1 | 3507 |

20995 7590 04/29/2010
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| EXAMINER |
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KIDWELL, MICHELE M

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| ART UNIT | PAPER NUMBER |
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3761

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| NOTIFICATION DATE | DELIVERY MODE |
|-------------------|---------------|

04/29/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/776,309 | Applicant(s) TAPADIYA, DILIP | |
| | Examiner Michele Kidwell | Art Unit 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,32,34-50,99-102,124 and 125 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31,32,34-50,99-102,124 and 125 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 15, 2010 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31, 34 – 48 and 124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6,311,838) in view of Smith et al. (US 6,402,724) and further in view of Greco (US 5,312,385).

With reference to claims 31 and 43 – 47, Johnson et al. (hereinafter "Johnson") discloses a packaging system for medical components that includes a sterilized container (10) configured to collect fluid during irrigation of a wound with a cover (20)

that is used to provide a seal over the kit thereby keeping the components within the kit in a sterilized state.

The difference between Johnson and claim 1 is the provision that the kit specifically includes a flexible sheet.

Smith et al. (hereinafter "Smith") teaches a wound irrigation shield that includes a flexible sheet with an adjustable aperture as set forth in the abstract. The shield may also be considered as being size to cover a wound area and a basin.

It would have been obvious to one of ordinary skill in the art to provide the kit of Johnson with the wound irrigation shield taught by Smith because Johnson discloses that the kit may include various types of medical devices and surgical equipment as set in the abstract. Likewise, the use of a kit is beneficial because all necessary supplies and equipment are packaged together for convenience and efficiency as taught by Johnson in col. 1, lines 15 – 19.

While Johnson does not specifically recite a basin made of biocompatible, hypoallergenic material, the examiner contends that it would have been obvious to one of ordinary skill in the art to sterilize the basin of Johnson and produce it with a biocompatible hypoallergenic material since Smith recognizes the benefit of providing a safe environment for the collection of bodily fluids (col. 1, lines 6 – 34).

Likewise, it would have been obvious to one of ordinary skill in the art to provide the device with biocompatible, hypoallergenic material in order to prevent an undesirable reaction between the patient and the product.

The difference between Johnson in view of Smith and claim 31 is the provision that the flexible sheet includes a material selected from a specific group.

Greco teaches a flexible sheet comprised from material from the claimed group as set forth in col. 4, lines 27 – 31.

It would have been obvious to one of ordinary skill in the art to provide the sheet of Smith with material from the claimed group because the material taught by Greco is transparent and capable of sterilization as taught by Greco in col. 4, lines 20 – 28.

As to claim 35, Smith discloses a flexible sheet having a shape selected from the group consisting of a circle, a square, a rectangle, a half-circle, a star and a diamond as set forth in figures 1, 3 and 5.

The difference between Johnson in view of Smith and claim 36 is the provision that the flexible sheet has a specific thickness.

Smith discloses a flexible sheet that would ultimately have a thickness.

It would have been obvious to one of ordinary skill in the art to modify the thickness of the sheet disclosed by Smith as desired since Smith acknowledges that the sheet may take any suitable form, size, shape, dimension and/or design as set forth in col. 5, lines 57 - 65.

Regarding claim 37, Smith discloses an irrigation kit wherein the flexible sheet is configured to have an umbrella shape as set forth in figures 1, 3 and 5.

As to claim 38, Smith discloses an irrigation kit wherein the flexible sheet is pleated to define an umbrella shape as set forth in figures 1, 3 and 5.

The difference between Johnson in view of Smith and claim 124 is the provision that the flexible sheet has a specific length.

Smith discloses a flexible sheet that has a length as set forth in the figures.

It would have been obvious to one of ordinary skill in the art to modify the length of Smith in order to determine the most effective product since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range includes only a level of ordinary skill in the art.

Regarding claims 40 – 42, see col. 7, lines 39 – 59.

With reference to claim 48, Smith discloses an irrigation kit further comprising a grommet (46) as set forth in col. 7, lines 11 – 14.

The difference between Johnson and Smith and claim 102 is the provision that the flexible sheet has a specific length.

Smith discloses a flexible sheet that has a length as set forth in the figures.

It would have been obvious to one of ordinary skill in the art to modify the length of the sheet disclosed by Smith as desired since Smith acknowledges that the sheet may take any suitable form, size, shape, dimension and/or design as set forth in col. 5, lines 57 - 65.

Claims 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6,311,838) in view of Smith et al. (US 6,402,724) and further in view of Barbut et al. (US 5,989,281).

The difference between Johnson in view of Smith and claim 32 is the provision that the kit includes a cannula having an adhesive surface.

Barbut et al. (hereinafter "Barbut") teaches a cannula that includes an adhesive portion as set forth in col. 24, lines 12 - 15.

It would have been obvious to one of ordinary skill in the art to modify the kit of Johnson to include a cannula with an adhesive surface because the adhesive allows necessary equipment to remain attached to the cannula without additional elements and because Johnson discloses that the kit may include various types of medical devices and surgical equipment as set in the abstract.

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holloway (US 5,381,562) and further in view of Smith et al. (US 6,402,724).

With reference to claim 49, Holloway discloses a basin that includes a surface with a convertible as set forth in col. 7, lines 3 - 15.

The difference between Holloway and claim 49 is the provision that the basin is comprised of specific materials and is included in a kit that also includes the claimed flexible sheet.

Smith et al. (hereinafter "Smith") teaches a wound irrigation shield that includes a flexible sheet with an adjustable aperture as set forth in the abstract.

Smith also seeks to provide a safe environment as set forth in col. 1, lines 6 – 34.

Holloway does not specifically recite a basin made of biocompatible, hypoallergenic material, however, the examiner contends that it would have been obvious to one of ordinary skill in the art to sterilize the basin of Holloway and produce it with a biocompatible hypoallergenic material since Smith recognizes the benefit of providing a safe environment for the collection of bodily fluids (col. 1, lines 6 – 34).

Likewise, it would have been obvious to one of ordinary skill in the art to provide the device with biocompatible, hypoallergenic material in order to prevent an undesirable reaction between the patient and the product.

Further, it would have been obvious to one of ordinary skill in the art to provide the basin of Holloway and the shield of Smith in a kit because it is well known in the art that the use of a kit is beneficial because all necessary supplies and equipment are packaged together for convenience and efficiency as taught as supported by the rejection of claim 31.

Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holloway (US 5,381,562) and in view of Smith et al. (US 6,402,724) and further in view of Robinson (US 3,407,957).

The difference between Holloway in view of Smith and claim 50 is the provision that the basin includes a convertible portion comprising a frangible portion.

Robinson teaches a frangible closure device for various containers as set forth in col. 1, lines 1 – 17.

It would have been obvious to one of ordinary skill in the art to modify the closure of Holloway with a frangible closure as taught by Robinson because the use of a frangible closure provides a tightly sealed closure as well as one that allows for easy accessibility and is inexpensive to manufacture as taught by Robinson in col. 2, lines 3 - 27.

Claims 99 – 102 and 125 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marogil (Des 386,684) in view of Smith et al. (US 6,402,724).

As to claim 99, Marogil discloses an irrigation device including a splash shield having a proximal collar and conical body that diverges in a distal direction always from the collar toward a distal rim as set forth in the figures.

The difference between Marogil and claim 99 is the provision that the splash shield is flexible and that the irrigation device includes an irrigation shield.

Smith teaches a flexible sheet configured to adapt to any number and variety of irrigation fluid delivery devices as set forth in the abstract.

It would have been obvious to one of ordinary skill in the art to provide the splash shield of Marogil with the flexible sheet taught by Smith because the use of such provides additional protection from backsplash during surgical procedures as taught by Smith in col. 3, lines 9 - 15.

Likewise, it would have been obvious to one of ordinary skill in the art to make the splash shield of Marogil flexible because the a flexible splash shield allows the shield to be manipulated to be formed about the unique shape of dimension of a user as taught by Smith in col. 3, lines 26 - 35.

With respect to claim 100, Smith discloses an elastically enlargeable opening as set forth in the abstract.

The difference between Marogil in view of Smith and claim 100 is the provision that the shield includes a latex portion.

It would have been obvious to one of ordinary skill in the art to provide the device of Marogil in view of Smith with a latex portion since the substitution of one type of elastic material for another is within the level of ordinary skill in the art.

As to claim 101, Smith discloses an irrigation kit wherein the flexible sheet is has an umbrella shape as set forth in figures 1, 3 and 5.

The difference between Marogil and Smith and claim 102 is the provision that the flexible sheet has a specific length.

Smith discloses a flexible sheet that has a length as set forth in the figures.

It would have been obvious to one of ordinary skill in the art to modify the length of the sheet disclosed by Smith as desired since Smith acknowledges that the sheet may take any suitable form, size, shape, dimension and/or design as set forth in col. 5, lines 57 - 65.

The difference between Marogil and Smith and claim 125 is the provision that the flexible sheet has a specific thickness.

Smith discloses a flexible sheet which has a thickness as set forth in the figures.

It would have been obvious to one of ordinary skill in the art to modify the thickness of the sheet disclosed by Smith as desired since Smith acknowledges that the sheet may take any suitable form, size, shape, dimension and/or design as set forth in col. 5, lines 57 - 65.

Response to Arguments

Applicant's arguments with respect to claims 31 – 32, 34 – 50, 99 – 102 and 124 – 125 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Kidwell whose telephone number is 571-272-4935. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michele Kidwell/
Primary Examiner, Art Unit 3761